

Amendments to the claims

18. Please amend claims 53 and 56 as follows:

- 5 Claim 1 (previously presented). A composition comprising one or more pellets for a timed or retarded release of a water-soluble nutritional supplement in the stomach and/or gastrointestinal tract of a human, wherein said one or more pellets comprise: an admixture of an effective amount of a nutritional supplement to be released at a controlled rate and a formulation comprising the components (1) a saccharide, (2) an excipient, (3) a lubricant, (4) an
- 10 agglutinative, (5) a stabilizing agent and (6) a plasticizer wherein,
- (1) said water-soluble nutritional supplement is present in an amount of about 60% to about 95% by weight;
- (2) said saccharide is present in an amount of about 1.5% to about 15% by weight;
- (3) said excipient is present in an amount of about .6% to about 6% by weight;
- 15 (4) said lubricant is present in an amount of about .07% to about 1% by weight;
- (5) said agglutinative is present in an amount of about .3% to about 3% by weight;
- (6) said stabilizing agent is present in an amount of about 1% to about 10% by weight; and
- (7) said plasticizer is present in an amount of about .1% to about 1% by weight.
- 20 Claim 2 (original). The composition according to claim 1 wherein:
- (1) said water-soluble nutritional supplement is present in an amount of about 75% to about 95% by weight;
- (1) said saccharide is present in an amount of about 3% to about 8% by weight;
- 25 (2) said excipient is present in an amount of about 1% to about 3% by weight;
- (3) said lubricant is present in an amount of about .15% to about .5% by weight;
- (4) said agglutinative is present in an amount of about .6% to about 1.5% by weight;
- (5) said stabilizing agent is present in an amount of about 2% to about 5% by weight; and
- 30 (6) said plasticizer is present in an amount of about .2% to about .5% by weight.

Claim 3 (original). The composition according to claim 2 wherein:

- (1) said water-soluble nutritional supplement is present in an amount of about 88% by weight;
- (2) said saccharide is present in an amount of about 5% by weight;
- (3) said excipient is present in an amount of about 1.8% by weight;
- (4) said lubricant is present in an amount of about .22% by weight;
- (5) said agglutinative is present in an amount of about 1.0% by weight;
- (6) said stabilizing agent is present in an amount of about 3.66% by weight; and
- (7) said plasticizer is present in an amount of about .35% by weight.

10 Claim 4 (previously presented). The composition according to claim 3 wherein said pellet(s) of said composition are inside a ~~gel~~ hard capsule.

15 Claim 5 (previously presented). The composition according to claim 1 wherein said water-soluble nutritional supplement is derived from a leaf, a root, or extract of a plant selected from one or more of the group consisting of: artichoke, bilberry, bioflavonoid, boswellia, bupleurium, chamomile, chlorophyll, cranberry, damiana, echinacea, essiac, garcinia cambogia, garlic, germanium, ginger, ginkgo, ginseng, goldenseal, grape seed, green tea, hawthorne berry, hesperidin, hops, horse chestnut, hydrangea, hypericum, indole-3-carbinol, licorice, lycopene, nettle root, peppermint, periwinkle, policosanol, psyllium, pygeum, quercetin, raspberry, 20 resveratol, rutin, sassafras, saw palmetto, silymarin, tribulus terrestris, turmeric, valerian, and wild yam or a nutraceutically acceptable salt, ether, ester, acid, or derivative thereof.

25 Claim 6 (previously presented). The composition according to claim 5 wherein said water-soluble nutritional supplement is selected from one or more of the group consisting of acetyl-l-carnosine, alpha lipoic acid, amylase, androstendiol, androstendione, arginine, ascorbic acid, B vitamin, beta-carotene, biotin, bromelain, calcium, chicken collagen, chitosan, choline, chondroitin, coenzyme Q10, creatine, dehydroepiandrosterone, diethylmethyaminoethanol, dihydroepiandrosterone, dimethylglycine, DMSO, gammahydroxybutric acid (GABA), glucosamine, glutamine, glutathione, hyaluronic acid, hydroxytryptophan, indium, isoleucine, l-

carnitine, lactoferrin, lecithin, leucine, lipase, lumbrokinase, lutein, magnesium, melatonin, Methylcobalamin, methylsulfonylmethane, MGN 3, ornithine, pancreatin, panthethoic acid, papain, para-amino benzoic acid (PABA), phenylalanine, phosphatidylcholine, phosphatidylserine, potassium, pregnenalone, protease, retinoic acid, retinol, s-adenosyl-methionine, selenium, taurine, theanine, thymase, tocopherol, trimethylglycine, tryptophan, tyrosine, valine, vinpocetine, vitamin D, vitamin A, zeathanthine, and zinc, or a nutraceutically acceptable salt, ether, ester, acid, or derivative thereof.

Claim 7 (original). The composition according to claim 6 wherein said water-soluble nutritional supplement comprises glucosamine sulfate, or nutraceutically acceptable salt, ether, ester, acid or derivative thereof.

Claim 8 (original). The composition according to claim 6 wherein said water-soluble nutritional supplement comprises chondroitin, or nutraceutically acceptable salt, ether, ester, acid or derivative thereof.

Claim 9 (original). The composition according to claim 1 wherein said saccharide comprises refined sugar.

Claim 10 (original). The composition according to claim 9 wherein said refined sugar is selected from one or more of the group consisting of beet sugar, brown sugar, cane sugar, caramel, caramelized sugar, corn sugar, granulated sugar, and fructose.

Claim 11 (original). The composition according to claim 1 wherein said saccharide comprises monosaccharides and disaccharides.

Claim 12 (original). The composition according to claim 11 wherein said monosaccharides and said disaccharides are selected from one or more of the group consisting of galactose, lactose, trehalose, sucrose, glucose, mannose, maltose, ribose, xylose and arabinose.

Claim 13 (original). The composition according to claim 1 wherein said excipient is selected from one or more of the group consisting of silicon dioxide, microcrystalline cellulose, calcium phosphate, calcium sulfate, sodium lauryl sulfate, silicified microcrystalline cellulose and silicon dioxide.

Claim 14 (original). The composition according to claim 13 wherein said excipient comprises silicon dioxide.

Claim 15 (original). The composition according to claim 1 wherein said lubricant is selected from one or more of the group consisting of magnesium stearate, stearic acid, and talc.

Claim 16 (original). The composition according to claim 15, wherein said lubricant comprises talc.

Claim 17 (original). The composition according to claim 1 wherein said agglutinative is selected from one or more of the group consisting of polyacrylates, polymethacrylates, polyvinylpyrrolidone, poly(vinyl acetate), various starches, corn products such as amaro, amylose and zein, pectin, alkoxylated celluloses, polyesters, polyethers, polyethylene glycol, proteins, nucleic acids, albumin, gelatin, starch, collagen, dextran and modified dextrans, polysaccharides, polylactide/polyglycolide, polyalkylcyanoacrylates, polyacrylamide, polysorbates, polyethylene ethers, polyethylene esters, polyoxyethylene/polyoxypropylene block polymers, cellulose acetophthalate, hydroxypropylmethyl cellulose phthalate, cellulose esters, cellulose diesters, cellulose triesters, cellulose ethers, cellulose ester-ether, cellulose acylate, cellulose diacylate, cellulose triacylate, cellulose acetate, cellulose diacetate, cellulose triacetate, cellulose acetate propionate, cellulose acetate butyrate, methyl cellulose, ethyl cellulose, hydroxyethyl cellulose, propyl cellulose, hydroxypropyl cellulose, lower-substituted hydroxypropyl cellulose, carboxymethyl cellulose, and hydroxypropylmethyl cellulose..

Claim 18 (original). The composition according to claim 17 wherein said agglutinative comprises hydroxypropylmethyl cellulose.

5 Claim 19 (original). The composition according to claim 1 wherein said stabilizing agent is selected from one or more of the group consisting of shellac and constituent aliphatic polyhydroxy acids of shellac, ascorbic acid, benzoic acid and fumaric acid.

Claim 20 (original). The composition according to claim 19 wherein said stabilizing agent comprises Shellac gum.

10 Claim 21 (original). The composition according to claim 1 wherein said plasticizer is selected from one or more of the group consisting of, adipate, azelate, enzoate, citrate, stearate, isoeubacate, sebacate, triethyl citrate, tri-n-butyl citrate, acetyl tri-n-butyl citrate, citric acid esters, triacetin, acetylated monoglyceride, grape seed oil, olive oil, sesame oil, acetyltributylcitrate, 15 acetyltriethylcitrate, glycerin sorbitol, diethyloxalate, diethylmalate, diethylfumarate, dibutylsuccinate, diethylmalonate, dioctylphthalate, dibutylsebacate, triethylcitrate, tributylcitrate, glyceroltributyrate and diethylphthalate.

20 Claim 22 (original). The composition according to claim 21 wherein said plasticizer comprises diethylphthalate.

25 Claim 23 (original). A composition comprising one or more pellets for a timed or retarded release of a water-soluble nutritional supplement in the stomach and/or gastrointestinal tract of a human, wherein said one or more pellets comprise: an admixture of an effective amount of a nutritional supplement to be released at a controlled rate and a formulation comprising the components (1) a saccharide, (2) an excipient, (3) a lubricant, (4) an agglutinative, and (5) a plasticizer wherein,

(1) said water-soluble nutritional supplement is present in an amount of about 60% to about 95% by weight;

- (2) said saccharide is present in an amount of about 1.5% to about 15% by weight;
- (3) said excipient is present in an amount of about .6% to about 6% by weight;
- (4) said lubricant is present in an amount of about .3% to about 3% by weight;
- (5) said agglutinative is present in an amount of about .3% to about 3% by weight;
- 5 (6) said plasticizer is present in an amount of about 1.5% to about 12% by weight.

Claim 24 (original). The composition according to claim 23 wherein:

- 10 (1) said water-soluble nutritional supplement is present in an amount of about 75% to about 95% by weight;
- (2) said saccharide is present in an amount of about 3% to about 8% by weight;
- (3) said excipient is present in an amount of about 1% to about 3% by weight;
- (4) said lubricant is present in an amount of about .15% to about .5% by weight;
- (5) said agglutinative is present in an amount of about .6% to about 1.5% by weight;
- 15 (6) said plasticizer is present in an amount of about 2% to about 6% by weight.

Claim 25 (original). The composition according to claim 24 wherein:

- 20 (1) said water-soluble nutritional supplement is present in an amount of about 88% by weight;
- (2) said saccharide is present in an amount of about 5% by weight;
- (3) said excipient is present in an amount of about 1.8% by weight;
- (4) said lubricant is present in an amount of about .22% by weight;
- (5) said agglutinative is present in an amount of about 1.0% by weight;
- 25 (6) said plasticizer is present in an amount of about 4% by weight.

Claim 26 (original). A composition comprising one or more pellets for a timed or retarded release capsule dosage of a water-soluble nutritional supplement, wherein said pellets comprise:
a core comprising:

- 30 about 62% to about 99% by weight of a water-soluble nutritional supplement;
- about 1.5% to about 16% by weight of a saccharide;

about .65% to about 6.5% by weight of an excipient;
about .05% to about .5% of a lubricant;
about .3% to about 3% by weight of an agglutivative; and
a semipermeable coating surrounding the core comprising:
5 about 20% to about 80% by weight of a lubricant;
about 25% to about 90% by weight of a stabilizing agent;
about 1.5% to about 15% by weight of a plasticizer.

Claim 27 (original). The composition according to claim 26 wherein:

10 said core comprises:

about 78% to about 99% by weight of said water-soluble nutritional supplement;
about 3% to about 8.3% by weight of said saccharide;
about 1% to about 3.3% by weight of said excipient;
15 about .05% to about .5% by weight of said lubricant;
about .6% to about 1.6% by weight of said agglutivative; and

said semipermeable coating surrounding said core comprises:

about 30% to about 50% by weight of said lubricant;
20 about 40% to about 60% by weight of said stabilizing agent;
about 3% to about 10% of said plasticizer.

Claim 28 (original). The composition according to claim 27 wherein:

25 said core comprises:

about 92% by weight of said water-soluble nutritional supplement;
about 5% by weight of said saccharide;
about 2% by weight of said excipient;
about .1% by weight of said lubricant;
30 about 1% by weight of said agglutivative; and

said semipermeable coating surrounding said core comprises:

about 42% by weight of said lubricant;

about 53% by weight of said stabilizing agent;
about 5% by weight of said plasticizer.

Claim 29 (original). The composition according to claim 26 wherein one or more of said
5 pellet(s) are inside of a gel capsule.

Claim 30 (previously presented). The composition according to claim 26 wherein said water-
soluble nutritional supplement is derived from a leaf, root, or extract of a plant selected from the
group consisting of artichoke, bilberry, bioflavonoid, boswella, bupleurium, chamomile,
10 chlorophyll, cranberry, damiana, echinacea, essiac, garcinia cambogia, garlic, germanium,
ginger, ginkgo, ginseng, goldenseal, grape seed, green tea, hawthorne berry, hesperidin, hops,
horse chestnut, hydrangea, hypericum, indole-3-carbinol, licorice, lycopene, nettle root,
peppermint, periwinkle, policosanol, psyllium, pygeum, quercetin, raspberry, resveratol, rutin,
sassafras, saw palmetto, silymarin, tribulus terrestris, turmeric, valerian, and wild yam; or a
15 nutraceutically acceptable salt, ether, ester, acid, or derivative thereof.

Claim 31 (previously presented). The composition according to claim 25 wherein said water-
soluble nutritional supplement is selected from one or more of the group consisting of acetyl-l-
carnosine, alpha lipoic acid, amylase, androstendiol, androstendione, arginine, ascorbic acid, B
20 vitamin, beta-carotene, biotin, bromelain, calcium, chicken collagen, chitosan, choline,
chondroitin, coenzyme Q10, creatine, dehydroepiandrosterone, diethylmethylaminoethanol,
dihydroepiandrosterone, dimethylglycine, DMSO, gammahydroxybutric acid (GABA),
glucosamine, glutamine, glutathione, hyaluronic acid, hydroxytryptophan, indium, isoleucine, l-
carnitine, lactoferrin, lecithin, leucine, lipase, lumbrokinase, lutein, magnesium, melatonin,
25 Methylcobalamin, methylsulfonylmethane, MGN 3, ornithine, pancreatin, panthethoic acid,
papain, para-amino benzoic acid (PABA), phenylalanine, phosphatidylcholine,
phosphatidylserine, potassium, pregnenolone, protease, retinoic acid, retinol, s-adenosyl-
methionine, selenium, taurine, theanine, thymase, tocopherol, trimethylglycine, tryptophan,
tyrosine, valine, vinpocetine, vitamin D, vitamin A, zeaxanthine, and zinc.; or a nutraceutically

acceptable salt, ether, ester, acid, or derivative thereof.

Claim 32 (original). The composition according to claim 26 wherein said saccharide comprises refined sugar.

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Claim 33 (original). The composition according to claim 32 wherein said refined sugar is selected from one or more of the group consisting of beet sugar, brown sugar, cane sugar, caramel, caramelized sugar, corn sugar, granulated sugar, and fructose.

10 Claim 34 (original). The composition according to claim 26 wherein said saccharide comprises monosaccharides and disaccharides.

15 Claim 35 (original). The composition according to claim 34 wherein said monosaccharides and said disaccharides are selected from one or more of the group consisting of galactose, lactose, trehalose, sucrose, glucose, mannose, maltose, ribose, xylose and arabinose.

20 Claim 36 (original). The composition according to claim 26 wherein said excipient is selected from one or more of the group consisting of silicon dioxide, microcrystalline cellulose, calcium phosphate, calcium sulfate, sodium lauryl sulfate, silicified microcrystalline cellulose and silicon dioxide.

Claim 37 (original). The composition according to claim 36 wherein said excipient comprises silicon dioxide.

25 Claim 38 (original). The composition according to claim 26 wherein said lubricant is selected from the group consisting of magnesium stearate, stearic acid, and talc.

Claim 39 (original). The composition according to claim 38 wherein said lubricant comprises talc.

Claim 40 (original). The composition according to claim 26 wherein said agglutinative is selected from one or more of the group consisting of polyacrylates, polymethacrylates, polyvinylpyrrolidone, poly(vinyl acetate), various starches, corn products such as amazo,
5 amylose and zein, pectin, alkoxylated celluloses, polyesters, polyethers, polyethylene glycol, proteins, nucleic acids, albumin, gelatin, starch, collagen, dextran and modified dextrans, polysaccharides, polylactide/polyglycolide, polyalkylcyanoacrylates, polyacrylamide, polysorbates, polyethylene ethers and esters, and polyoxyethylene/polyoxypropylene block
10 polymers, cellulose acetophthalate, hydroxypropylmethyl cellulose phthalate, cellulose esters, cellulose diesters, cellulose triesters, cellulose ethers, cellulose ester-ether, cellulose acylate, cellulose diacylate, cellulose triacylate, cellulose acetate, cellulose diacetate, cellulose triacetate, cellulose acetate propionate, cellulose acetate butyrate, methyl cellulose, ethyl cellulose, hydroxyethyl cellulose, propyl cellulose, hydroxypropyl cellulose, lower-substituted hydroxypropyl cellulose, carboxymethyl cellulose, and hydroxypropylmethyl cellulose.

15 Claim 41 (original). The composition according to claim 40 wherein said agglutinative comprises hydroxypropylmethylcellulose.

20 Claim 42 (original). The composition according to claim 26 wherein said stabilizing agent is selected from the group consisting of shellac and its constituent aliphatic polyhydroxy acids, ascorbic acid, benzoic acid and fumaric acid.

25 Claim 43 (previously presented). The composition according to claim 42 wherein said stabilizing agent comprises sShellac gum.

Claim 44 (original). The composition according to claim 26 wherein said plasticizer is selected from one or more of the group consisting of, adipate, azelate, enzoate, citrate, stearate, isoebucate, sebacate, triethyl citrate, tri-n-butyl citrate, acetyl tri-n-butyl citrate, citric acid esters, triacetin, acetylated monoglyceride, grape seed oil, olive oil, sesame oil, acetyltributylcitrate,

acetyltriethylcitrate, glycerin sorbitol, diethyloxalate, diethylmalate, diethylfumarate, dibutylsuccinate, diethylmalonate, dioctylphthalate, dibutylsebacate, triethylcitrate, tributylcitrate, glyceroltributyrate and diethylphthalate.

5 Claim 45 (original). The composition according to claim 44 wherein said plasticizer comprises diethylphthalate.

Claim 46 (original). A composition comprising one or more pellets for a timed or retarded release capsule dosage of a water-soluble nutritional supplement, wherein said pellets comprise:

10 a core comprising:

about 92% by weight of said water-soluble nutritional supplement;

about 5% by weight of said saccharide;

about 2% by weight of said excipient;

15 about .1% by weight of said lubricant;

about 1% by weight of said agglutinative; and

said semipermeable coating surrounding said core comprises:

about 97% by weight of said plasticizer;

20 about 2.25% by weight of said lubricant;

Claim 47 (original). The composition according to claim 46 wherein said water-soluble nutritional supplement comprises chondroitin.

25 Claim 48 (original). The composition according to claim 1 wherein the timed or retarded release dosage release pellet exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C +/- 0.5 degree:

after 1 hour about 10% to about 30% of said nutritional supplement is released;

after 4 hours about 50% to about 75% of said nutritional supplement is released; and

30 after 8 hours about 75% to about 95% of said nutritional supplement is released;

after 12 hours about 80% to about 100% of said nutrition supplement is released.

Claim 49 (withdrawn). The composition according to claim 1 wherein the timed or retarded release dosage release pellet exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C +/- 0.5 degree:

- 5 after 1 hour about 19% of said nutritional supplement is released;
after 4 hours about 59% of said nutritional supplement is released;
after 8 hours about 81% of said nutritional supplement is released; and
after 12 hours about 88% of said nutritional supplement is released.
- 10 Claim 50 (previously presented). The composition according to claim 1 wherein the timed or retarded release dosage release pellet exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C +/- 0.5 degree:
after 1 hour about 15% to about 35% of said nutritional supplement is released;
after 4 hours about 45% to about 75% of said nutritional supplement is released; and
15 after 8 hours about 75% to about of 95% said nutritional supplement is released;
after 12 hours about 80% to about 100% of said nutritional supplement is released.

- Claim 51 (withdrawn). The composition according to claim 1 wherein the timed or retarded release dosage release pellet exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C +/- 0.5 degree:
- 20 after 1 hour about 30% of said nutritional supplement is released;
after 4 hours about ~~5~~69% of said nutritional supplement is released;
after 8 hours about 88% of said nutritional supplement is released; and
after 12 hours about 96% of said nutritional supplement is released.

- 25 Claim 52 (original). The composition according to claim 1 wherein the timed or retarded release dosage release pellet exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C +/- 0.5 degree: 90% is released after about 8 hours.

Claim 53 (currently amended). A method of producing a composition of one or more pellets for a timed or retarded release capsule dosage of a water-soluble nutritional supplement comprising at least one controlled release pellet comprising the steps of:

- 5 (a) weighing the water-soluble nutritional supplement formulation components, wherein said formulation components comprise a saccharide, an excipient, a lubricant, an agglutinative, a stabilizer and a plasticizer, such that the following proportions are present by weight:

the nutritional supplement is about 60% to 95% by weight;

the saccharide is about 1.5% to about 15% by weight;

- 10 the excipient is about .6% to about 6% by weight;

the lubricant is about .07% to about 1% by weight;

the agglutinative is about .3% to about 3% by weight;

Shellac Gum is about 1% to about 10% by weight; and

the plasticizer is about .1%- 1% by weight;

- 15 (b) preparing a solution with said agglutinative;

(c) preparing a mixture with the excipient and half of the lubricant

(d) adding said mixture of excipient and lubricant to the saccharide and about one half of said solution of the agglutinative;

(e) forming said pellets from the mixture of step (d);

- 20 (f) drying said pellets;

(g) applying the water-soluble nutritional supplement using the remainder of the agglutinative solution to make the pellets ~~fast release~~;

(h) drying the pellets after the application is complete;

(i) preparing a solution using the stabilizer, plasticizer and the other half of the lubricant;

- 25 (j) applying solution of step (i) to the ~~fast release~~ pellets to form the timed or retarded release pellets;

(k) drying the pellets;

(l) assaying the ~~fast release~~ pellets and the timed or retarded release pellets in a solution of gastric pH; and

(m) adjusting the amounts of said formulations components to attain the desired timed or retarded release.

Claim 54 (original). The method according to claim 49 wherein said composition of one or more
5 said pellets for a timed or retarded release capsule dosage of said water-soluble nutritional
supplement exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm
in 900 ml of water at 37 degree C +/- 0.5 degree:

after 1 hours about 10% to about 30% of the nutritional supplement is released; and

after 4 hours about 50% to about 75% of said nutritional supplement is released;

10 after 8 hours about 75% to about 95% of said nutritional supplement is released;

after 12 hours about 80% to about 100% of said nutritional supplement is released.

Claim 55 (withdrawn). The method according to claim 50 wherein said composition of one or
more pellets for a timed or retarded release capsule dosage of said water-soluble nutritional
15 supplement exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm
in 900 ml of water at 37 degree C +/- 0.5 degree:

after 1 hour about 19% of the nutritional supplement is released;

after ~~2~~ 4 hours about 59% of the nutritional supplement is released;

after ~~3~~ 8 hours about 81% of the nutritional supplement is released; and

20 after ~~4~~ 12 hours about 88% of the nutritional supplement is released.

Claim 56 (currently amended). A method of producing a composition of one or more pellets for
a timed or retarded release capsule dosage of a water-soluble nutritional supplement comprising
at least one controlled release pellet comprising the steps of:

25 (a) weighing the water-soluble nutritional supplement formulation components, wherein said
formulation components comprise a saccharide, an excipient, a lubricant, an agglutinative, and a
plasticizer, such that the following proportions are present by weight:

the nutritional supplement is about 60% to 95% by weight;

the saccharide is about 1.5% to about 15% by weight;

the excipient is about .6% to about 6% by weight;
the lubricant is about .3 % to about 3% by weight;
the agglutinative is about .3% to about 3% by weight;
the plasticizer is about 1.5 % to about 12 % by weight;

- 5 (b) preparing a solution with said agglutinative;
(c) preparing a mixture with the excipient and half of the lubricant;
(d) adding said mixture of excipient and lubricant to the saccharide and about one half of said solution of the agglutinative;
(e) forming said pellets from the mixture of step (d);
10 (f) drying said pellets;
(g) applying the water-soluble nutritional supplement using the remainder of the agglutinative solution to make the pellets ~~fast-release~~;
(h) drying the pellets after the application is complete;
(i) preparing a solution using the plasticizer and the other half of the lubricant;
15 (j) applying solution of step (i) to the ~~fast-release~~ pellets to form the timed or retarded release pellets;
(k) drying the pellets;
(l) assaying the ~~fast-release~~ pellets and the timed or retarded release pellets in a solution of gastric pH; and
20 (m) adjusting the amounts of said formulations components to attain the desired timed or retarded release.

Claim 57 (previously presented). The method according to claim 56 wherein said composition of one or more said pellets for a timed or retarded release capsule dosage of said water-soluble nutritional supplement exhibits the following dissolution profile when tested in a No. 2 (paddle)
25 at 50 rpm in 900 ml of water at 37 degree C +/- 0.5 degree after 1 hour about 15% to about 45% of the nutritional supplement is released:

after 1 hour about 15% to about 35% of said nutritional supplement is released; and
after 4 hours about ~~45~~5% to about 75% of said nutritional supplement is released;

after 8 hours about 75% to about 95% of said nutritional supplement is released;
after 12 hours about 80% to about 100% said nutritional supplement is released.

Claim 58 (withdrawn). The method according to claim 57 wherein said composition of one or
5 more pellets for a timed or retarded release capsule dosage of said water-soluble nutritional
supplement exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm
in 900 ml of water at 37 degree C +/- 0.5 degree:

after 1 hour about 30% of the nutritional supplement is released;
after 4 hours about 56.9% of the nutritional supplement is released;
10 after 8 hours about 88% of the nutritional supplement is released; and
after 12 hours about 96% of the nutritional supplement is released.

Claim 59 (original). A method of analyzing a composition of one or more pellets for a timed or
retarded release capsule dosage of a glucosamine sulfate sodium chloride form comprising at
15 least one controlled release pellet comprising:

performing chromatography on said pellets wherein,
at least 10 capsules containing pellets are weighed individually and the average weight of
their content is determined to be between about 1269.02 to about 1460
mg/capsule;
20 the mean is determined and the relative standard deviation is not more than about 6%,
about 20 mg of glucosamine sulfate sodium chloride is weighed and transferred
quantitatively to a 25 ml volumetric flask; water is added to complete the
volume;
the solution is filtered through a 0.45 micron an HVLP membrane and injected three
25 times into a liquid chromatograph;
the relative standard deviation is not more than about 2%;
about 40 mg of glucosamine sulfate sodium chloride is weighed and transferred to
a 50 ml volumetric flask;
30 water is added to complete volume;

the solution is filtered through a .45 micron HVLP membrane and injected twice into a liquid chromatograph;

the relative standard deviation is not more than about 2%; and

filtering said pellets wherein

5 the content of a capsule is crushed and transferred quantitatively to a 500 ml volumetric flask;

200 ml of water is added;

the solution is placed in an ultrasonic Triturate for about 15 minutes;

water is added to complete the volume and mixed well

10 the solution is filtered through a .45 micron HVLP membrane and injected once.

Claim 60 (original). A method for treating arthritis in a mammal comprising the administration of the composition according to claim 1 wherein said water-soluble nutritional supplement comprises a nutraceutically effective dose of glucosamine, its nutraceutically acceptable salts, ethers, esters, acid, or other derivatives.

Claim 61 (original). A method for maintaining healthy bones and joints in a mammal comprising the administration of the composition according to claim 1 wherein said water-soluble nutritional supplement comprises a nutraceutically effective dose of glucosamine, its nutraceutically acceptable salts, ethers, esters, acid, or other derivatives.

Claim 62 (original). The method according to claim 56 wherein said glucosamine is provided in a dose ranging from about 100 mg to about 2000 mg per day.

25 Claim 63 (original). The method according to claim 56 wherein said glucosamine is provided in a dose of about 500 mg per day.

Claim 64 (original). A method for treating arthritis in a mammal comprising the administration of the composition according to claim 1 wherein said water-soluble nutritional supplement

comprises a nutraceutically effective dose of chondroitin, its nutraceutically acceptable salts, ethers, esters, acid, or other derivatives..

5 Claim 65 original). A method for maintaining healthy bones and joints in a mammal comprising the administration of the composition according to claim 1 wherein said water-soluble nutritional supplement comprises a nutraceutically effective dose of chondroitin, its nutraceutically acceptable salts, ethers, esters, acid, or other derivatives.

10 Claim 66 (original). The method according to claim 65 wherein said chondroitin is provided in a dose ranging from about 100 mg to about 2000 mg per day.

Claim 67 (original). The method according to claim 66 wherein said glucosamine is provided in a dose of about 500 mg per day.